IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 8337**
Osamu JOHDO et al.	:	Docket No. 2000_0694A
Serial No. 09/555,494	:	Group Art Unit 1634
Filed June 1, 2000	:	Examiner Bradley L. Sisson

CRYSTALLINE ANTHRACYCLINE ANTIBIOTIC
AND PROCESS FOR PRODUCING THE SAME

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is responsive to the Official Action dated January 15, 2003, the time for responding thereto being extended for two months in accordance with a petition for extension submitted concurrently herewith.

Reconsideration is respectfully requested in view of the following remarks.

The present invention is directed to a novel crystalline form of daunomycin hydrochloride. Other forms of daunomycin hydrochloride have been known in the prior art, as described on pages 1-2 of the specification, however such forms have typically had high hygroscopicity and poor stability. The novel crystalline form of daunomycin hydrochloride having the characteristic to 2θ values according to the claims has low hygroscopicity and excellent chemical stability.

Claims 7-15 are rejected under 35 USC 103 as being unpatentable Umezawa et al. This ground of rejection is respectfully traversed.

Umezawa et al. fail to disclose the compound according to the claims. The claims are directed to daunomycin hydrochloride. On the other hand, Umezawa et al. is directed to the free base form of daunomycin.

Accordingly, Umezawa et al. does not disclose or suggest the novel crystalline form of daunomycin hydrochloride according to claim 7.

As noted by the Examiner, column 7 of Umezawa et al. disclose the use of organic solvents that are miscible with water, and specifically discloses the use of butanol, methanol, ethanol and acetone.

However, Umezawa et al. teach using an organic solvent miscible with water solely for the purpose of extracting the free base form of daunomycin from microbial cells.

Umezawa et al. then teach filtering the solids, and subjecting the filtrate to an organic solvent such as chloroform or ethyl acetate. See column 7, lines 36-38.

As noted by the Examiner, Umezawa et al. disclose forming a daunomycin powder at column 9.

However, Umezawa et al. teach forming the powder by extracting the daunomycin with chloroform, and then concentrating the daunomycin with an excess of n-hexane to cause precipitation.

Thus, Umezawa et al. teach forming a daunomycin using a chloroform/n-hexane solvent system, which is an oleophilic solvent system.

Umezawa et al. fail to disclose or suggest preparing the crystalline form of daunomycin according to the claimed invention, using a water miscible organic solvent system, which is a hydrophilic solvent system, using a first solvent comprising 1-butanol.

Thus, Umezawa et al. neither teach nor suggest that an "organic solvent miscible with water such as acetone methanol, ethanol, butanol, etc." in the above-quoted passage of column 7 is effectively usable for the crystallization of daunomycin hydrochloride.

Besides, Umezawa et al. disclose neither the claimed crystalline form of daunomycin hydrochloride, nor even a powder thereof. Of course, it would have been quite impossible to predict, from Umezawa et al., that daunomycin hydrochloride could be obtained having such characteristic 2θ values as specified in claims, or having such characteristic features of excellent stability and low hygroscopicity as noted above, based upon the teachings of Umezawa et al.

Accordingly, it is respectfully submitted that the cited reference fails to disclose or suggest the claimed invention. Reconsideration and allowance is solicited.

Respectfully submitted,

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June 16, 2003